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Food Protection Program
Policies, Procedures and Guidelines

Issue:	**Herbal/Dietary Supplements**	**No: RF - 07**

"Dietary supplement" as defined in the Dietary Supplement Health and Education Act (DSHEA) of 1994 is a product taken by mouth that contains a "dietary ingredient" intended to supplement the diet. The "dietary ingredients" in these products may include: vitamins, minerals, herbs or other botanicals, amino acids, and substances such as enzymes, organ tissues, glandulars, and metabolites. Dietary supplements can be extracts or concentrates, and may be found in many forms such as tablets, capsules, softgels, gelcaps, liquids or powders. Whatever the form, DSHEA places dietary supplements in a special category under the umbrella of "foods", not drugs, and requires that every supplement be labeled a dietary supplement.

The local board of health has the authority, under 105 CMR 590.00: State Sanitary Code, Chapter X-Minimum Standards for Food Establishments, to permit dietary supplement businesses as the DSHEA places them under the umbrella of foods. Permitting would follow food-manufacturing guidelines as with any other food product. Dietary supplements in general have not been implicated in food borne illness outbreaks and therefore may be considered non-PHF (potentially hazardous food) foods for consideration in limited preparation in residential kitchens. Depending upon the nature of the intended marketing, the residential kitchen may be permitted by either the local board of health if retailing or, if wholesaling is intended, by the Massachusetts Department of Public Health (DPH).

Physical attributes of the manufacturing areas should be similar for any other food products. It is strongly recommended that products be labeled with some type of shelf date or expiration date, which is supported by scientific data or testing. Natural herbs and supplements may lose effectiveness over time. U.S. Food and Drug Administration (FDA) regulations require that dietary supplement labels must include a descriptive name of the product stating that it is a supplement, the name and place of business of the manufacturer, packer, or distributor, a complete list of ingredients, and the net contents of the product. In addition, each dietary supplement (except for eligible small businesses) must have a nutrition label in the form of a "Supplemental Facts" label. This label must identify each dietary ingredient contained in the product.

Another labeling issue is that of claims; a dietary supplement cannot promote on its label or in any informational labeling that it is a treatment, a prevention, or a cure for a specific disease or condition. Dietary supplements may make "health related" claims (such as promotes restful

sleep, increases energy); the manufacturer is responsible for the validity of these claims. The law says that if a dietary supplement makes a "health related" claim, it must state in a "disclaimer" that FDA has not evaluated this claim. It must also state that this product is not intended to "diagnose, treat, cure, or prevent any disease", because only a drug can make such a claim.

In accordance with DSHEA, the manufacturer of all dietary supplements is responsible for the safety of their products. Complaints about dietary supplements, as well as over the counter medications and cosmetics, should be sent to DPH/DFD who will forward to FDA for follow-up, as FDA is the primary enforcement agency for these products.